

# Collaborative randomised controlled trial of trigger versus conventional ventilation in preterm infants with respiratory distress syndrome

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/10/2014	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.refer.nhs.uk/ViewRecord.asp?ID=193>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Harry Baumer

### Contact details

Plymouth Hospitals NHS Trust  
Derriford Hospital  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH  
+44 (0)1752 763450  
[harry.baumer@phnt.swest.nhs.uk](mailto:harry.baumer@phnt.swest.nhs.uk)

## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

C/6/16-04-94/BAUMER/F

## **Study information**

**Scientific Title**

### **Study objectives**

Objectives: To investigate the effects of Patient Triggered Ventilation (PTV) compared with conventional ventilation (Intermittent Mandatory Ventilation [IMV]) in preterm infants ventilated for Respiratory Distress Syndrome (RDS).

Setting: Twenty-two neonatal intensive care units.

Design: Subjects were 924 babies under 32 weeks gestation and within 72 hours of birth ventilated for RDS for less than 6 hours. Telephone randomisation to receive either PTV or IMV. Analysis on "intention to treat" basis.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Neonatal diseases

### **Interventions**

1. Trigger ventilation
2. Conventional ventilation

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Death before discharge home or oxygen therapy at 36 weeks gestation
2. Pneumothorax whilst ventilated
3. Cerebral ultrasound abnormality nearest 6 weeks
4. Duration of ventilation in survivors

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/11/1994

**Completion date**

31/03/1998

## Eligibility

**Key inclusion criteria**

Infants of less than 32 weeks gestation, they are ventilated within 72 hours of birth, and have features compatible with respiratory distress syndrome

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

924

**Key exclusion criteria**

Babies with evidence of major congenital malformation or evidence of inhalational pneumonitis will be excluded

**Date of first enrolment**

01/11/1994

**Date of final enrolment**

31/03/1998

## Locations

### Countries of recruitment

England

United Kingdom

### Study participating centre

**Plymouth Hospitals NHS Trust**

Plymouth

United Kingdom

PL6 8DH

## Sponsor information

### Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

### Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

### Sponsor type

Government

### Website

<http://www.doh.gov.uk>

## Funder(s)

### Funder type

Government

### Funder Name

# Results and Publications

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2000		Yes	No